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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, April 15, 2015 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	May 20, 2015

MEMBERS PRESENT

Kenneth Sellers, Public Member, President
Susan Esposito, R.Ph., Professional Member, Vice President
Joli Martini, R.Ph., Professional Member
Kimberly Robbins, R.Ph., Professional Member
Bonnie Wallner, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Julia Wheatley, Public Member
Jay Galloway, Public Member

MEMBERS ABSENT

Hooshang Shanehsaz, R.Ph., Professional Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General
David Dryden, Executive Secretary
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Nehal Parikh
Zack Green
Mark Madachik
Suzanne Rabb-Long
Bhavin Patel
Dale Clarke
Nancy Sawyer
Jaime Frink
Mary Choi
Leon Rapuano III
Phil Anderson
Nneoma Ndubuisi
Cheryl Heiks
Paul J Danielraj

CALL TO ORDER

Mr. Sellers called the meeting to order at 9:30 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Martini and seconded by Ms. Robbins, to approve the meeting minutes for March 18, 2015. The motion unanimously carried.

PRESIDENT'S REPORT

No Report

UNFINISHED BUSINESS

Complaint Status

13-09-11 – Assigned to Hearing Officer
13-12-11 – Assigned to Hearing Officer
13-19-11 – Forwarded to Office of Attorney General
13-01-13 – Forwarded to Office of Attorney General
13-04-13 – Forwarded to Office of Attorney General
13-05-13 – Forwarded to Office of Attorney General
13-06-13 – Forwarded to Office of Attorney General
13-20-13 – Forwarded to Office of Attorney General
13-26-13 – Assigned to Hearing Officer
13-01-14 – Forwarded to Office of Attorney General
13-03-14 – Assigned
13-04-14 – Assigned
13-05-14 – Assigned
13-06-14 – Forwarded to Office of Attorney General
13-07-14 – Forwarded to Office of Attorney General
13-08-14 – Assigned
13-09-14 – Forwarded to Office of Attorney General
13-10-14 – Forwarded to Office of Attorney General
13-11-14 – Forwarded to Office of Attorney General
13-12-14 – Forwarded to Office of Attorney General
13-13-14 – Assigned
13-14-14 – Forwarded to Office of Attorney General
13-15-14 – Assigned
13-16-14 – Assigned
13-17-14 – Assigned

Re-Review of Proposal to Deny

None

Proposal to Deny Hearing

None

Re-Review of Tabled Applications

PharMedium Services applications for locations: Texas, New Jersey, Mississippi, and Tennessee. A motion was made by Ms. Martini and seconded by Ms. Esposito to propose to deny the application for Texas. The motion carried unanimously. A motion was made by Ms. Esposito and Ms. Robbins to propose to deny the applications for New Jersey, Mississippi and Tennessee. The motion unanimously carried.

Leiter's Enterprises dba: Leiter's Compounding. A motion to approve was made by Ms. Robbins and seconded by Ms. Martini. The motion unanimously carried.

Virtus Pharmaceuticals, LLC. A motion to approve was made by Ms. Robbins and seconded by Ms. Wallner. The motion unanimously carried.

Statutory and Regulatory Discussion

- Practitioner/Pharmacy Ownership. Ms. Kelly will prepare draft statute changes for the Board to review during the next meeting in May.
- DEA Federal Disposal Rules nothing reported. This item is no longer required and has been requested to be removed from the agenda.
- Provision for Disciplinary Action. Ms. Kelly will add citation causes to statutes where applicable. Mr. Dryden will provide feedback on other states statutes regarding fines, citations and the types of infractions that would incur them. The Board asked that the administrative costs be recoverable and added to the fine. The Board would like fine language to reflect “minimum of \$500.00 fine for each violation” to be included in the statute. The Board also requested to include the ability to issue citations for violations. The Board has requested to add permanent revocation as an option for discipline. Ms. Kelly will continue to research similar states statute for further information for the Board to review.
- Pharmacy Technician Regulation. The committee has concluded that a statutory change be formulated to require all in-state pharmacies to obtain criminal history reports for all employees that have access to the pharmacy. The records would need to be available for inspection upon request.
- Clarification of §2512(e)(f), Inactive Status, Ms. Kelly will review the current statutory language and provide the Board draft language to clarify the 4 year requirement. She will also provide clarification language for rules and regulations changes to define requirements for returning to active status.
- Legality of Pharmacies Providing Kickbacks to Prescribers in Exchange for Referrals, the Board determined that no further discussion is required at this time and asked that this item be removed from the agenda.
- Review of Crimes Listing. A motion was made by Ms. Esposito seconded by Mr. Galloway to have the Legislative Committee review the crimes listing to make recommendations for changes. The motion unanimously carried.

NEW BUSINESS

Mr. Sellers read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist: A1-0004725 Sharona-Stephanie Mahta Wasserman

A1-0004726 Arti Patel

A1-0004727 Ha Na Kim

A1-0004728 Andrew Gene Gibson

A1-0004729 Andrew B. Clayborne

A1-0004730 John P. Dolan

A1-0004731 Virbala A Patel

A1-0004732 Michelle Patricia Bauer

A1-0004733 Alex L. Keller

A1-0004734 Jerry Allan Bliss

A1-0004735 Ayman M. Yousef

A1-0004736 Irene Ji Kim

A motion was made by Ms. Esposito and seconded by Ms. Wheatley to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern: A7-0002387 Austyn Taylor Grim

A7-0002388 Maria Fidelis Ilagan Romero

A motion was made by Ms. Esposito and seconded by Ms. Wheatley to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001603 Innovative Pharmacy

A9-0001604	Personal Support Medical Suppliers
A9-0001605	Y Medical Associates, Inc.
A9-0001606	Tech-Pharmaceuticals, Inc. dba Vidascript
A9-0001607	Ashland Health
A9-0001608	Independence Holding Company LLC
A9-0001609	Encino Pharmacy
A9-0001610	Sunflower Discount Pharmacy, LLC
A9-0001611	Simple Meds LLC
A9-0001612	Partners IV and Ancillary Healthcare Services
A9-0001613	Apogee Bio-Pharm LLC
A9-0001614	Palm Beach Pharma Corp.
A9-0001615	Nufactor, Inc.
A9-0001616	Apothecary Services, Inc. dba Rosemont Pharmacy
A9-0001617	Cityplex Pharmacy DBA Pharmacy and Nutrition Shoppe
A9-0001618	Diamondback Drugs

A motion was made by Ms. Martini and seconded by Ms. Patel to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0001184	Sanofi-Aventis U.S. LLC
A4-0002179	Fisher Bioservices Inc.
A4-0002180	Reckitt Benckiser LLC
A4-0002181	The Procter & Gamble Distributing LLC
A4-0002182	The Procter & Gamble Distributing LLC
A4-0002183	The Procter & Gamble Distributing LLC
A4-0002184	Healix Infusion Therapy, Inc.
A4-0002185	Southern Anesthesia & Surgical, Inc.
A4-0002186	Questcor Pharmaceuticals, Inc.
A4-0002188	Sanofi-aventis U.S. LLC

A motion was made by Ms. Martini and seconded by Ms. Patel to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000121	New Jersey Rehab Medicine Inc
A2-0000122	Persante Continuing Care
A2-0000123	Ultra Medical Supply, Inc.
A2-0000124	AHP Knoxville Partnership
A2-0000125	Med-Equip, Inc
A2-0000126	US Med, Inc.

A motion was made by Ms. Martini and seconded by Ms. Patel to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0000981	PRMC Home Scripts Millsboro
A3-0000982	Progressive Health Services, LLC dba United Pharmacy

A motion was made by Ms. Martini and seconded by Ms. Patel to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Retail Pharmacy Temporary Licensure Approval Ratification

None

Outsourcing Facility

None

Pharmacist-In-Charge Interviews

A motion to amend the agenda was made by Ms. Martini and seconded by Ms. Robbins to add the following PIC interviewees to the agenda: Nehal Parikh, Wal-Mart Wilmington, De.

The motion carried unanimously.

Ms. Robbins conducted PIC interviews with:
Paul J Danielraj, United Pharmacy Milton, DE
Nneoma Ndubuisi, Target Christiana Mall, Newark, De.
Mary Choi, Kmart Pharmacy #4807 Bear, De
Mark Madachik, Walmart Cheswold, De.
Nehal Parikh, Wal-Mart Wilmington, De.

Consultant Pharmacist Interviews

None

Review of Consent Agreement

A consent agreement for Albert Giodano was reviewed by the Board. A motion was made by Ms. Robbins and seconded by Mr. Galloway to accept the consent agreement as presented. The motion carried unanimously.

Review of Applications by DAG

Pharmacy Board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received, followed by the Board ruling:

Facility: Paragon Enterprises. A motion was made by Ms. Robbins and seconded by Mr. Galloway to approve the application. The motion unanimously carried.

Facility: Crescent Health Care. A motion was made by Ms. Robbins and seconded by Mr. Galloway to approve the application. The motion unanimously carried.

Facility: Safeway Pharmacy 4702. A motion was made by Ms. Martini and seconded by Ms. Wheatley to approve the application. The motion unanimously carried.

Review of CE Received

Michael Volstorf provided a continuing education approval request for classes held at University of Southern Florida. A motion was made by Ms. Wallner seconded by Ms. Esposito to approve 2 CEU's of the program classified as "Patient Safety".

FDA Compounding Memorandum of Understanding (MOU)

Mr. Dryden stated that he and Mr. Hooshang Shanehsaz attended the FDA meeting in Washington in March. Mr. Dryden stated that the FDA wants a MOU completed for any dispensing of sterile compounded drugs over state lines in excess of 20% of the facilities business. The FDA is looking for support from the states to support this initiative. Mr. Dryden will provide the Board a copy of the MOU for review and this will be kept on the agenda as a standing item for discussion.

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden

Mr. Dryden provided the Board a copy of HB69 relating to Telemedicine for review. This legislation is currently being presented for approval.

Continuing Education – Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

No Report

Consumer Affairs – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

Professional Liaisons – Kim Robbins and Tejal Patel:

Ms. Robbins reported that the Delaware Pharmacists Society annual conference will be held on May 11 – 13, 2015 in Dewey Beach, De. Ms. Robbins stated that Mr. Hooshang Shanehsaz will be doing a presentation on Controlled Substances during the convention. Ms. Robbins also requested to be removed from the committee due to conflicting schedules. Mr. Sellers appointed Mr. Hooshang Shanehsaz as her replacement on the committee.

Controlled Substance Liaisons – Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

No Report

Patient Safety Committee – Michelle McCreary (Chair), Kenneth Sellers, Tejal Patel, Kimberly Robbins, Susan Esposito, Joli Martini, Hooshang Shanehsaz, Jay Patel

No Report. There is a meeting scheduled immediately following this Board meeting.

COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Tejal Patel, Brenda Pavlic, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

Mr. Dryden and Ms. Kelly will be meeting to clarify and finalize draft rules and regulations following federal guidelines.

Pharmacy Technician Licensure Committee – Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle, Susan Esposito and David Dryden:

No Report

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

No Report

BOARD CORRESPONDENCE

Mr. Dryden provided requested feed-back to the Board regarding Downing Labs involvement with over \$18k in unwanted billing for pain medications. The Board of Pharmacy does not have any jurisdiction over this incident until and/or unless it occurs in Delaware and a formal complaint is filed.

EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

Mr. Dryden reported that the PMP is currently in the final stages of the approval of the contract with University of Delaware. Once approved, the GEO-Mapping project can begin.

Mr. Dryden attended the Board of Directors meeting at NASCSA in Boston.

The Controlled Substance Registration renewals have been released for processing. The renewal will provide feedback on practitioner dispensing throughout Delaware. There is also a mandatory course for all practitioners with a controlled substance registration that must be completed. This course is offered for free on the Division of Professional Regulations website as well as on the Medical Society's Website (for a fee).

An email was received from Rite-Aid inquiring about pharmacists providing buccal swapping. Is this allowed in Delaware? Mr. Dryden stated that §2502 does not allow for this practice.

Mr. Dryden shared with the Board the passing of previous Board member Mr. Joseph Kukulich.

Ms. McCreary reported that she has completed 13 inspections since the last meeting. 8 routine, 2 New, 1 FDA, and 1 DEA inspection.

NEWSLETTER UPDATES

May 2015 newsletter has been submitted for processing for release in the beginning of May.

OTHER BUSINESS BEFORE THE BOARD

Ms. Martini asked if the application approval process can be reviewed to become more streamlined and possibly reduce the number of applications the Board would need to review. She suggested that possibly a separate committee could review the applications. Mr. Galloway stated he felt the process was streamlined

pretty effectively. Ms. Mast stated that the final approval processes are in the process to begin utilizing electronic devices to be used during meetings in lieu of all of the paper files. Ms. Mast expressed that if a committee was formed to approve applications that they would be required to meet every month, in order to prevent applications from being held up from processing. The consensus is to continue the current process and continue to bring suggestions for improvement to the Board. The members of the Board all expressed concern regarding issues with accessing encrypted documents.

PUBLIC COMMENT

Mr. Phil Anderson stated that the “Delaware Tele-health Coalition” meets quarterly. The next meeting is October 20, 2015 at the University of Delaware. Mr. Anderson suggested that the Board consider having a member attend the next meeting. The group works on legislative decisions that could be benefited by participation from the Board.

Mr. Anderson was asked about the closing of Walgreens stores. He stated that Walgreens closes and opens stores throughout the year and that the company should stay consistent with current store numbers.

NEXT SCHEDULED MEETING

The next meeting is scheduled for May 20, 2015 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Ms. Esposito, seconded by Ms. Patel at 11:51 am.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast", written in a cursive style.

Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy